

## **REMARKS**

### **Status of the Claims.**

Applicants note that an amendment was filed on March 29, 2005 (identified by the Examiner as filed on March 25, 2005). A Notice of Non-Compliant Amendment was mailed on April 19, 2005, and this was followed by an Office Action mailed on June 23, 2005. In the June 23, 2005 Office Action, the Examiner indicated that the amendment filed on March 25, 2005 [March 29, 2005] was entered.

Accordingly, Applicants understand that claims 1-18, 38, 39, 47, 49, and 56-67 are pending with entry of this amendment, claims 19-37, 40-46, 48, and 50-55 being previously canceled and claims 63-67 being previously added. Claims 1, 38, and 47 amended herein. These amendments introduce no new matter. Support is replete throughout the specification, *e.g.* in the claims as originally filed, at page 53, lines 6-7, and the like.

### **35 U.S.C. §112, first paragraph (Office Action Paragraph 3).**

Claims 1-18, 63, 65, and 67, were rejected under 35 U.S.C. §112, first paragraph, because the specification while enabling for methods where a "YKL-40 level greater than the 95th percentile for normal control YKL-40 levels is an indicator of reduced survival expectancy . . ." is allegedly not enabling for methods where any increased level is used as such an indicator.

Claims 1, 38, and 47 are amended herein to recite that the elevation is greater than the 95 percentile level thereby obviating this rejection. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

### **35 U.S.C. §112, first paragraph, written description (Office Action Paragraph 4).**

Claims 47, 49, 56-62, and 66 were rejected under 35 U.S.C. §112, first paragraph, for failing to provide a written description of the claimed invention. In particular, the Examiner alleged that the limitation of "said assay 'wherein said elevation is unrelated to known causes of YKL-40 elevation other than cancer'" claimed in claim 47 has no clear support in the specification and the claims as originally filed. Applicants traverse.

The specification at page 59, lines 4-9, expressly states:

Serum YKL-40 can identify patients with cancer before clinical symptoms appear, and therefore before the cancer would normally be discovered. In a routine screening application of the YKL-40 assay, cases of anomalous elevations of YKL-40 (that is, **unrelated to known causes of elevation other than cancer**) would merit rigorous follow up tests to determine the location of the cancer. Such tests are not normally carried out on apparently healthy people, but would be justified if serum YKL-40 is elevated.

and thus clearly provides support for the language in amended claim 47. Accordingly the rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

**35 U.S.C. §112, first paragraph (Office Action Paragraph 5).**

Claims 1-9, 11-18, 38-39, 63-65, and 67 were rejected under 35 U.S.C. §112, first paragraph, because the specification, ". . . while enabling for the claimed methods comprising obtaining a biological fluid sample for the measurement of YKL-40 . . ." was allegedly not enabling for methods involving other types of biological samples.

To expedite prosecution, independent claims 1, and 38 are amended herein so they are directed to methods utilizing a "biological **fluid**" thereby obviating this rejection. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

**Claim Objections (Office Action Paragraph 6).**

Claim 49 was objected to because it appeared that an additional copy of the claim was inserted under the amended claim. This is corrected herein thereby obviating this objection.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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Respectfully submitted,



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